IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TEVA PHARMACEUTICALS USA, INC., TEVA PHARMACEUTICAL INDUSTRIES LTD., and TEVA NEUROSCIENCE, INC.

Plaintiffs,

v.

SANDOZ INC.

Defendant.

Civil Action No.: 1:17-cv-00597-GMS

JURY TRIAL DEMANDED
FOR ALL ISSUES SO TRIABLE

[redacted]

Redacted Version : Filed June 16, 2017

DEFENDANT SANDOZ INC.'S ANSWER, DEFENSES AND COUNTERCLAIMS

Defendant Sandoz Inc. ("Sandoz" or "Defendant") hereby submits this Answer, Defenses, and Counterclaims ("Answer") to the Complaint filed by Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries Ltd., and Teva Neuroscience, Inc. ("Teva" or "Plaintiffs") in *Teva Pharm. USA, Inc. et al. v. Sandoz Inc. et al.*, 17-cv00275-FLW-DEA (D.N.J.) on January 13, 2017, which was ultimately transferred to this district and assigned the above captioned civil action number. *See Teva Pharm. USA, Inc. et al. v. Sandoz Inc. et al.*, 17-cv-00275-FLW-DEA (D.N.J.), D.I. 90.

GENERAL DENIAL

Pursuant to Fed. R. Civ. P. 8(b)(3), Sandoz denies all allegations in Teva's Complaint except those specifically admitted below.

NATURE OF THE ACTION

1. This is an action by Teva for infringement of United States Patent No. 9,155,775 ("the '775 patent") arising under the patent laws of the United States, Title 35, United States Code. This action arises out of Sandoz's ongoing attempt to market, manufacture and sell a generic version of COPAXONE® 40 mg/mL, 1 mL syringe, injection

("COPAXONE®"), Teva's innovative treatment for patients with relapsing-remitting forms of multiple sclerosis, prior to the expiration of the '775 patent.

ANSWER: Paragraph 1 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Sandoz admits that Teva purports to state a claim for alleged infringement arising under the patent laws of the United States. Except as expressly admitted herein, the allegations of Paragraph 1 are denied.

THE PARTIES

Teva

2. Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation with its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454-1090.

ANSWER: On information and belief, Sandoz admits that Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation with its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454-1090. Except as expressly admitted herein, the allegations of Paragraph 2 are denied.

3. Teva Pharmaceutical Industries Ltd. ("Teva Ltd.") is an Israeli company with its principal place of business at 5 Basel Street, P.O. Box 3190, Petah Tikva, 49131, Israel.

ANSWER: On information and belief, Sandoz admits that Teva Pharmaceutical Industries Ltd. ("Teva Ltd.") is an Israeli company and has a principal place of business at 5 Basel Street, P.O. Box 3190, Petah Tikva, 49131, Israel. Except as expressly admitted herein, the allegations of Paragraph 3 are denied.

4. Teva Neuroscience, Inc. ("Teva Neuroscience") is a Delaware corporation with its principal place of business at 11100 Nall Ave, Overland Park, KS 66211.

ANSWER: On information and belief, Sandoz admits that Teva Neuroscience, Inc. ("Teva Neuroscience"), is a Delaware corporation with its principal place of business at 11100 Nall Ave.,

Overland Park, Kansas 66211. Except as expressly admitted herein, the allegations of Paragraph 4 are denied.

Sandoz

5. Upon information and belief, Sandoz Inc. is a corporation organized and existing under the laws of Colorado with its principal place of business at 100 College Rd. West, Princeton, NJ 08540.

ANSWER: Sandoz admits that Sandoz Inc. is a corporation organized and existing under the laws of Colorado with its principal place of business at 100 College Rd. West, Princeton, NJ 08540. Except as expressly admitted herein, the allegations of Paragraph 5 are denied.

6. Upon information and belief, Momenta Pharmaceuticals, Inc. is a corporation organized and existing under the laws of Delaware with its principal place of business at 675 West Kendall Street, Cambridge, MA 02142.

ANSWER: Sandoz is without sufficient knowledge or information to form a belief as to the truth of the allegations contained in Paragraph 6 of the Complaint, and on that basis denies each and every allegation contained therein.

JURISDICTION AND VENUE

7. This action for patent infringement arises under 35 U.S.C. § 271.

ANSWER: Paragraph 7 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Sandoz admits that this action purports to be an action arising under the patent laws of the United States. Except as expressly admitted herein, the allegations of Paragraph 7 are denied.

8. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

ANSWER: Paragraph 8 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Sandoz admits that this action alleges subject matter

jurisdiction under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202. Except as expressly admitted herein, the allegations of Paragraph 8 are denied.

9. Venue is proper in this Judicial District under 28 U.S.C. §§ 1391 and 1400(b).

ANSWER: Paragraph 9 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Sandoz denies the allegations of Paragraph 9. Further answering, Sandoz agrees not to contest venue in the District of Delaware solely for purposes of this action only. Except as expressly admitted herein, the allegations of Paragraph 9 are denied.

10. Teva sells COPAXONE® throughout the United States, including within the State of New Jersey.

ANSWER: Sandoz is without sufficient knowledge or information to form a belief as to the truth of the allegations contained in Paragraph 10 of the Complaint, and on that basis denies each and every allegation contained therein.

Personal Jurisdiction Over Sandoz Inc.

11. Upon information and belief, this Court has personal jurisdiction over Sandoz Inc.

ANSWER: Paragraph 11 contains legal conclusions and allegations to which no answer is required. Paragraph 11 is vague to the extent "this Court" could mean Delaware or New Jersey given the recent transfer of this matter to Delaware. To the extent an answer is required, Sandoz denies the allegations of Paragraph 11. Further answering, Sandoz agrees not to contest personal jurisdiction in the District of Delaware solely for purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party, including Teva. Except as expressly admitted herein, the allegations of Paragraph 11 are denied.

12. Upon information and belief, Sandoz Inc. is a company with its principal place of business in the State of New Jersey.

ANSWER: Paragraph 12 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Sandoz admits that Sandoz Inc. is a corporation organized and existing under the laws of Colorado with its principal place of business at 100 College Rd. West, Princeton, NJ 08540. Except as expressly admitted herein, the allegations of Paragraph 12 are denied.

13. Upon information and belief, Sandoz Inc. markets, distributes and/or sells generic drugs within the State of New Jersey and throughout the United States.

ANSWER: Paragraph 13 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Sandoz denies that it is subject to personal jurisdiction in this case in New Jersey or Delaware merely by reason of marketing, distribution or selling generic drugs within the State of New Jersey and/or Delaware. Further answering, Sandoz agrees not to contest personal jurisdiction in the District of Delaware solely for purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party, including Teva. Except as expressly admitted herein, the allegations of Paragraph 13 are denied.

14. Upon information and belief, Sandoz Inc. has engaged in and maintained systematic and continuous business contacts within the State of New Jersey, and has purposefully availed itself of the benefits and protections of the laws of New Jersey rendering it at home in New Jersey.

ANSWER: Paragraph 14 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Sandoz denies that it is subject to personal jurisdiction in this case and for the reasons alleged in this Paragraph. Further answering, Sandoz agrees not to contest personal jurisdiction in the District of Delaware solely for purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party, including Teva. Except as expressly admitted herein, the allegations of Paragraph 14

are denied.

15. Upon information and belief, Sandoz Inc. routinely files Abbreviated New Drug Applications ("ANDAs") with the U.S. Food & Drug Administration ("FDA") and markets dozens of generic pharmaceutical products in the State of New Jersey, including, *inter alia*, amoxicillin-clavulanate potassium, atorvastatin calcium, decitabine, ceftriaxone sodium, and clindamycin phosphate.

ANSWER: Paragraph 15 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Sandoz admits that it has filed Abbreviated New Drug Applications (or "ANDAs") with the United States Food and Drug Administration (or "FDA") in Maryland, seeking approval for various pharmaceutical products, including quality generic medicines. To the extent this Paragraph is alleged to seek to justify jurisdiction in New Jersey, the issue is moot given the transfer of this case to the District of Delaware. Further answering, Sandoz agrees not to contest personal jurisdiction in the District of Delaware solely for purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party, including Teva. Except as expressly admitted herein, the allegations of Paragraph 15 are denied.

16. Upon information and belief, Sandoz Inc. has agreements with pharmaceutical retailers, wholesalers or distributors providing for the distribution of its products in the State of New Jersey, including, *inter alia*, amoxicillin-clavulanate potassium, atorvastatin calcium, decitabine, ceftriaxone sodium, and clindamycin phosphate.

ANSWER: Paragraph 16 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, to the extent this Paragraph was alleged to seek to justify jurisdiction in New Jersey, the issue is moot given the transfer of this case to the District of Delaware. Further answering, Sandoz agrees not to contest personal jurisdiction in the District of Delaware solely for purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party, including Teva. Sandoz denies the

allegations of Paragraph 16.

17. Upon information and belief, Sandoz Inc. has committed or will imminently commit acts that aid, abet, contribute to and/or constitute tortious patent infringement that will harm and injure Teva, which manufactures COPAXONE® 40 mg/mL product for sale and use throughout the United States, including the State of New Jersey.

ANSWER: Paragraph 17 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, to the extent this Paragraph was alleged to seek to justify jurisdiction in New Jersey, the issue is moot given the transfer of this case to the District of Delaware. Sandoz denies the allegations of Paragraph 17.

18. Teva sells COPAXONE® 40 mg/mL product in the State of New Jersey.

ANSWER: Sandoz is without sufficient knowledge or information to form a belief as to the truth of the allegations contained in Paragraph 18 of the Complaint, and on that basis, denies each and every allegation contained therein. Further answering, to the extent this Paragraph was alleged to seek to justify jurisdiction in New Jersey, the issue is moot given the transfer of this case to the District of Delaware.

19. Upon information and belief, Sandoz Inc. has applied for FDA approval to market and sell a generic version of COPAXONE® 40 mg/mL product throughout the United States, including in New Jersey.

ANSWER: Paragraph 19 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Sandoz admits that it filed an ANDA seeking FDA approval to manufacture and sell glatiramer acetate injection 40 mg/mL ("Sandoz's ANDA Product" or "Sandoz 40 mg ANDA Product"). To the extent this Paragraph was alleged to seek to justify jurisdiction in New Jersey, the issue is moot given the transfer of this case to the District of Delaware. Except as expressly admitted herein, the allegations of Paragraph 19 are denied.

20. Upon information and belief, Sandoz Inc. will market, sell, and offer for sale its proposed generic version of COPAXONE® 40 mg/mL product in the State of New

Jersey following FDA approval of that product.

ANSWER: Paragraph 20 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Sandoz admits that it filed an ANDA seeking FDA approval to manufacture and sell Sandoz's 40 mg ANDA Product. To the extent this Paragraph was alleged to seek to justify jurisdiction in New Jersey, the issue is moot given the transfer of this case to the District of Delaware. Except as expressly admitted herein, the allegations of Paragraph 20 are denied.

21. Upon information and belief, as a result of Sandoz Inc.'s marketing, selling, or offering for sale of its generic version of COPAXONE® 40 mg/mL product in the State of New Jersey, Teva will lose sales of COPAXONE® 40 mg/mL product and be injured in the State of New Jersey.

ANSWER: Paragraph 21 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Sandoz denies the allegations of Paragraph 21. To the extent this Paragraph was alleged to seek to justify jurisdiction in New Jersey, the issue is moot given the transfer of this case to the District of Delaware.

22. Upon information and belief, this Court also has personal jurisdiction over Sandoz Inc. because it previously has been sued in this district, did not challenge this Court's assertion of personal jurisdiction over it, and availed itself of the rights, benefits, and privileges of this forum by asserting counterclaims for the purpose of litigating patent infringement disputes. *See, e.g., Helsinn Healthcare S.A. et al. v. Dr. Reddy's Laboratories, et al.*, C.A. No. 13-05815 (D.N.J.); *Janssen Pharmaceuticals, Inc. et al. v. Sandoz Inc. et al.*, C.A. No. 13-06929 (D.N.J.); *Cornerstone Therapeutics Inc. et al. v. Sandoz Inc.*, C.A. No. 13-05723 (D.N.J.); *Boehringer Ingelheim Pharma et al. v. Sandoz Inc., et al.*, C.A. 15-7461 (D.N.J.); *Otsuka Pharm. Co. v. Sandoz Inc.*, C.A. No. 15-1716 (D.N.J.); *Amag Pharms., Inc. v. Sandoz Inc.*, C.A. 16-1508 (D.N.J.), *Immunex Corp. et al. v Sandoz Inc., et al.*, C.A. No. 16-1118 (D.N.J.); *Sanofi-Aventis U.S. LLC et al. v. Sandoz Inc.*, C.A. 16-5678 (D.N.J.).

ANSWER: Paragraph 22 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, to the extent this Paragraph was alleged to seek to justify jurisdiction in New Jersey, the issue is moot given the transfer of this case to the District

of Delaware. Further answering, Sandoz agrees not to contest personal jurisdiction in the District of Delaware solely for purposes of this action only and expressly reserves the right to contest personal jurisdiction in any other case as to any other party, including Teva. Sandoz admits that it has been sued in the District of New Jersey and has asserted counterclaims, including in the actions identified in this paragraph. Except as expressly admitted herein, the allegations of Paragraph 22 are denied.

23. Upon information and belief, this Court has personal jurisdiction over Sandoz Inc. for the reasons stated herein, including, *inter alia*, Sandoz Inc.'s activities in the forum, activities directed at the forum, and significant contacts with the forum, all of which render Sandoz Inc. at home in this forum.

ANSWER: Paragraph 23 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, to the extent this Paragraph was alleged to seek to justify jurisdiction in New Jersey, the issue is moot given the transfer of this case to the District of Delaware. Further answering, Sandoz agrees not to contest personal jurisdiction in the District of Delaware solely for purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party, including Teva. Except as expressly admitted herein, the allegations of Paragraph 23 are denied.

Personal Jurisdiction Over Momenta Pharmaceuticals Inc.

24. Upon information and belief, this Court has personal jurisdiction over Momenta Pharmaceuticals, Inc.

ANSWER: Paragraph 24 contains legal conclusions and allegations directed to a third party to which no answer is required. To the extent an answer is required, Sandoz is without sufficient knowledge or information to form a belief as to the truth of the allegations contained in Paragraph 24 of the Complaint, and on that basis, denies each and every allegation contained therein.

25. Upon information and belief, Momenta Pharmaceuticals, Inc. markets, distributes and/or sells generic drugs within the State of New Jersey and throughout the United States.

ANSWER: Paragraph 25 contains legal conclusions and allegations directed to a third party to which no answer is required. To the extent an answer is required, Sandoz is without sufficient knowledge or information to form a belief as to the truth of the allegations contained in Paragraph 25 of the Complaint, and on that basis, denies each and every allegation contained therein.

26. Upon information and belief, Momenta Pharmaceuticals, Inc. has engaged in and maintained systematic and continuous business contacts within the State of New Jersey, and has purposefully availed itself of the benefits and protections of the laws of New Jersey rendering it at home in New Jersey.

ANSWER: Paragraph 26 contains legal conclusions and allegations directed to a third party to which no answer is required. To the extent an answer is required, Sandoz is without sufficient knowledge or information to form a belief as to the truth of the allegations contained in Paragraph 26 of the Complaint, and on that basis, denies each and every allegation contained therein.

27. Upon information and belief, Momenta Pharmaceuticals, Inc., through its business partner, Sandoz Inc., has agreements with pharmaceutical retailers, wholesalers or distributors providing for the distribution of its products in the State of New Jersey, including, *inter alia*, enoxaparin sodium and glatiramer acetate.

ANSWER: Paragraph 27 contains legal conclusions and allegations directed to a third party to which no answer is required. To the extent an answer is required, Sandoz is without sufficient knowledge or information to form a belief as to the truth of the allegations contained in Paragraph 27 of the Complaint, and on that basis, denies each and every allegation contained therein.

28. Upon information and belief, Momenta Pharmaceuticals, Inc. has committed or will imminently commit acts that aid, abet, contribute to and/or constitute

tortious patent infringement that will lead to harm and injury to Teva, which manufactures COPAXONE® 40 mg/mL product for sale and use throughout the United States, including the State of New Jersey.

ANSWER: Paragraph 28 contains legal conclusions and allegations directed to a third party to which no answer is required. To the extent an answer is required, Sandoz denies the allegations of Paragraph 28.

29. Teva sells COPAXONE® 40 mg/mL product in the State of New Jersey.

ANSWER: Paragraph 29 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Sandoz is without sufficient knowledge or information to form a belief as to the truth of the allegations contained in Paragraph 29 of the Complaint, and on that basis, denies each and every allegation contained therein. Further answering, to the extent this Paragraph was alleged to seek to justify jurisdiction in New Jersey, the issue is moot given the transfer of this case to the District of Delaware.

30. Upon information and belief, Momenta Pharmaceuticals, Inc. (through its business partner Sandoz Inc.) has applied for FDA approval to market and sell a generic version of COPAXONE® 40 mg/mL product throughout the United States, including in New Jersey.

ANSWER: Paragraph 30 contains legal conclusions and allegations directed to a third party to which no answer is required. To the extent an answer is required, to the extent this Paragraph was alleged to seek to justify jurisdiction in New Jersey, the issue is moot given the transfer of this case to the District of Delaware. Further answering, Sandoz agrees not to contest personal jurisdiction in the District of Delaware solely for purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party, including Teva. Sandoz admits that it filed an ANDA seeking FDA approval to manufacture and sell Sandoz's 40 mg ANDA Product. Sandoz further admits that Momenta Pharmaceuticals, Inc.

("Momenta") is Sandoz's collaboration partner for the development and commercialization of Sandoz's 40 mg ANDA Product. Except as expressly admitted herein, the allegations of Paragraph 30 are denied.

31. Upon information and belief, Momenta Pharmaceuticals, Inc. (through its business partner Sandoz Inc.) will market, sell, and offer for sale its proposed generic version of COPAXONE® 40 mg/mL product in the State of New Jersey following FDA approval of that product.

ANSWER: Paragraph 31 contains legal conclusions and allegations directed to a third party to which no answer is required. To the extent an answer is required, to the extent this Paragraph was alleged to seek to justify jurisdiction in New Jersey, the issue is moot given the transfer of this case to the District of Delaware. Further answering, Sandoz agrees not to contest personal jurisdiction in the District of Delaware solely for purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party, including Teva. Sandoz admits that Sandoz and Momenta are development and commercialization partners for Sandoz's 40 mg ANDA Product. Except as expressly admitted herein, the allegations of Paragraph 31 are denied.

32. Upon information and belief, as a result of Momenta Pharmaceuticals, Inc.'s (through its business partner Sandoz Inc.) marketing, selling, or offering for sale of its generic version of COPAXONE® 40 mg/mL product in the State of New Jersey, Teva will lose sales of COPAXONE® 40 mg/mL product and be injured in the State of New Jersey.

ANSWER: Paragraph 32 contains legal conclusions and allegations directed to a third party to which no answer is required. To the extent an answer is required, to the extent this Paragraph was alleged to seek to justify jurisdiction in New Jersey, the issue is moot given the transfer of this case to the District of Delaware. Sandoz denies the allegations of Paragraph 32.

33. Upon information and belief, this Court has personal jurisdiction over Momenta Pharmaceuticals, Inc. for the reasons stated herein, including, *inter alia*, Momenta Pharmaceuticals, Inc.'s activities in the forum, activities directed at the forum,

and significant contacts with the forum, all of which render Momenta Pharmaceuticals, Inc. at home in the forum.

ANSWER: Paragraph 33 contains legal conclusions and allegations directed to a third party to which no answer is required. To the extent an answer is required, to the extent this Paragraph was alleged to seek to justify jurisdiction in New Jersey, the issue is moot given the transfer of this case to the District of Delaware. Sandoz is without sufficient knowledge or information to form a belief as to the truth of the allegations contained in Paragraph 33 of the Complaint, and on that basis, denies each and every allegation contained therein.

34. Upon information and belief, following any FDA approval of Sandoz's ANDA, Sandoz Inc. and Momenta Pharmaceuticals, Inc. will work in concert with one another to make, use, offer to sell, and sell a generic version of COPAXONE® 40 mg/mL product throughout the United States, including in New Jersey.

ANSWER: Paragraph 34 contains legal conclusions and allegations directed to a third party to which no answer is required. To the extent an answer is required, to the extent this Paragraph was alleged to seek to justify jurisdiction in New Jersey, the issue is moot given the transfer of this case to the District of Delaware. Further answering, Sandoz admits that Sandoz and Momenta are development and commercialization partners for Sandoz's 40 mg ANDA Product. Except as expressly admitted herein, the allegations of Paragraph 34 are denied.

35. Upon information and belief, Momenta Pharmaceuticals, Inc. will manufacture Sandoz's proposed generic version of COPAXONE® 40 mg/mL product on behalf of Sandoz Inc. and Sandoz Inc. will act as the agent of Momenta Pharmaceuticals, Inc. for sale of that product in the United States, including New Jersey.

ANSWER: Paragraph 35 contains legal conclusions and allegations directed to a third party to which no answer is required. To the extent an answer is required, to the extent this Paragraph was alleged to seek to justify jurisdiction in New Jersey, the issue is moot given the transfer of this case to the District of Delaware. Sandoz admits that Sandoz and Momenta are development and commercialization partners for Sandoz's 40 mg ANDA Product. Except as

expressly admitted herein, the allegations of Paragraph 35 are denied.

BACKGROUND

The '775 Patent

36. The '775 patent, entitled "Process for Manufacturing Glatiramer Acetate Product," was duly and legally issued to Teva Ltd. by the United States Patent and Trademark Office on October 13, 2015, and expires on January 28, 2035. The '775 Patent has 27 claims.

ANSWER: Paragraph 36 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Sandoz admits that, according to the electronic records of the United States Patent and Trademark Office ("Patent Office"), the '775 patent is entitled "Process for Manufacturing Glatiramer Acetate Product" and, on its face, identifies a purported issue date of October 13, 2015, and further purports to have 27 issued claims. Sandoz denies that the '775 patent was duly and legally issued by the Patent Office. Except as expressly admitted herein, the allegations of Paragraph 36 are denied.

37. Rakefet Cohen, Sasson Habbah, and Muhammad Safadi are named inventors of the '775 patent.

ANSWER: Paragraph 37 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, according to the electronic records of the Patent Office, Sandoz admits that the '775 patent lists, on its face, Rakefet Cohen, Sasson Habbah, and Muhammad Safadi as the purported named inventors. Except as expressly admitted herein, the allegations of Paragraph 37 are denied.

38. Teva Ltd. is the sole owner, by assignment, of all rights, title and interest in the '775 patent.

ANSWER: Paragraph 38 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Sandoz is without sufficient knowledge or information to form a belief as to the truth of the allegations contained in Paragraph 38 of the

Complaint, and on that basis, denies each and every allegation contained therein.

39. Teva Ltd. has granted Teva USA an exclusive license under the '775 patent to use, offer to sell, sell and import the COPAXONE 40 mg/mL product in the United States.

ANSWER: Paragraph 39 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Sandoz is without sufficient knowledge or information to form a belief as to the truth of the allegations contained in Paragraph 39 of the Complaint, and on that basis, denies each and every allegation contained therein.

40. A true and correct copy of the '775 patent is attached as Exhibit A.

ANSWER: Sandoz admits that Exhibit A to the Complaint purports to be a copy of the '775 patent. Except as expressly admitted herein, the allegations of Paragraph 40 are denied.

Teva's COPAXONE® 40 mg/mL Product

41. Plaintiffs researched, developed, applied for and obtained FDA approval to manufacture, sell, promote and/or market COPAXONE® 40 mg/ml product.

ANSWER: Paragraph 41 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Sandoz admits that the electronic version of FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the "Orange Book"), identifies "TEVA PHARMACEUTICALS USA" as the purported "Applicant Holder" for approved New Drug Application ("NDA") No. 20622 for, inter alia, COPAXONE® (Glatiramer Acetate) Injection 40 mg/mL. Sandoz is without sufficient knowledge or information to form a belief as to the truth of the remaining allegations contained in Paragraph 41 of the Complaint, and on that basis, denies each and every allegation contained therein.

42. Teva USA is the holder of New Drug Application ("NDA") number 20-622, approved by the United States Food and Drug Administration ("FDA") for the use of glatiramer acetate 40 mg/mL three times per week, marketed as COPAXONE® 40 mg/mL, for the treatment of patients with relapsing forms of multiple sclerosis such as relapsing-remitting multiple sclerosis.

ANSWER: Paragraph 42 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Sandoz admits that the electronic version of FDA's Orange Book identifies "TEVA PHARMACEUTICALS USA" as the purported "Applicant Holder" for approved New Drug Application ("NDA") No. 20622 for, inter alia, COPAXONE® (Glatiramer Acetate) Injection 40 mg/mL. Sandoz further admits that the current FDA-approved label states, inter alia: "COPAXONE (glatiramer acetate injection) is indicated for the treatment of patients with relapsing forms of multiple sclerosis"; and "COPAXONE 40 mg per mL: administer three times per week and at least 48 hours apart." Except as expressly admitted herein, the allegations of Paragraph 42 are denied.

43. Teva's innovative COPAXONE® 40 mg/mL product is supplied as single-dose prefilled syringes that contain 40 mg/ml glatiramer acetate for injection, manufactured by Teva Ltd., and marketed and sold in the United States by Teva Neuroscience.

ANSWER: Paragraph 43 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Sandoz admits that the current FDA-approved label states, inter alia: "Injection: 40 mg per mL in a single-dose, prefilled syringe with a blue plunger. For subcutaneous use only." Except as expressly admitted herein, the allegations of Paragraph 43 are denied.

44. The active drug ingredient in COPAXONE® 40 mg/mL is glatiramer acetate. Glatiramer acetate is a complex mixture of polypeptide chains made from four amino acid building blocks. The individual polypeptide chains in glatiramer acetate vary in length and the sequence in which the amino acids are connected together.

ANSWER: Paragraph 44 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Sandoz admits that the active ingredient in COPAXONE® Injection 40 mg/mL is generically known as "glatiramer acetate." Sandoz further admits that the current FDA-approved label states, inter alia: "Glatiramer acetate, the active

ingredient of COPAXONE, consists of the acetate salts of synthetic polypeptides, containing four naturally occurring amino acids: L-glutamic acid, L-alanine, L-tyrosine, and L-lysine with an average molar fraction of 0.141, 0.427, 0.095, and 0.338, respectively." Except as expressly admitted herein, the allegations of Paragraph 44 are denied.

45. The invention claimed in the '775 patent reflects, in part, the discovery that filtering pharmaceutical preparations of glatiramer acetate at temperatures of above 0° C to 17.5° C improves the filtration process used to manufacture pharmaceutical preparations and facilitates the commercial production of COPAXONE® 40 mg/mL.

ANSWER: Sandoz denies the allegations of Paragraph 45.

46. Teva practices at least one of the claims of the '775 patent in manufacturing COPAXONE® 40 mg/mL. In manufacturing COPAXONE® 40 mg/mL, Teva, *inter alia*, filters an aqueous pharmaceutical solution of glatiramer acetate and mannitol at a temperature of above 0° C to 17.5° C to produce a filtrate with improved filterability compared to the filterability of the solution at room temperature.

ANSWER: Paragraph 46 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Sandoz is without sufficient knowledge or information to form a belief as to the truth of the allegations contained in Paragraph 46 of the Complaint, and on that basis, denies each and every allegation contained therein.

The Sandoz ANDA

47. Sandoz filed an ANDA under 21 U.S.C. § 355(j) seeking FDA approval to manufacture, use, offer for sale, sell in and import into the United States glatiramer acetate injection, 40 mg/mL, purported to be generic to Teva's COPAXONE® 40 mg/mL product ("Sandoz's Glatiramer Acetate Product" or "Defendants' Glatiramer Acetate Product").

ANSWER: Paragraph 47 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Sandoz admits that it filed an ANDA seeking FDA approval to manufacture and sell Sandoz's 40 mg ANDA Product. Sandoz further admits that the reference listed drug for Sandoz's 40 mg ANDA Product is COPAXONE® (Glatiramer Acetate) Injection 40 mg/mL. Except as expressly admitted herein, the allegations of Paragraph

47 are denied.

48. FDA assigned the ANDA for Sandoz's Glatiramer Acetate Product the number 206921.

ANSWER: Sandoz admits that FDA assigned No. 20-6921 to the ANDA for Sandoz's 40 mg ANDA Product. Except as expressly admitted herein, the allegations of Paragraph 48 are denied.

49. Upon information and belief, both Sandoz Inc. and Momenta Pharmaceuticals, Inc. submitted, collaborated and/or acted in concert in the preparation or submission of ANDA No. 206921.

ANSWER: Paragraph 49 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Sandoz admits that Sandoz and Momenta are development and commercialization partners for Sandoz's 40 mg ANDA Product. Except as expressly admitted herein, the allegations of Paragraph 49 are denied.

50. In order to be approved by the FDA, the drug product described in an ANDA must be equivalent to the innovator drug product in dosage form, strength, route of administration, quality, performance characteristics, and intended use.

ANSWER: Paragraph 50 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Sandoz admits that the approval requirements for an ANDA are fully set forth in the applicable statute and FDA's implementing rules and regulations. Except as expressly admitted herein, the allegations of Paragraph 50 are denied.

51. In order to be approved by the FDA, the active ingredient in an ANDA product must be "the same as" the innovator's active ingredient. Thus, generic applicants must scientifically demonstrate that the active ingredient in their product is "the same as" the active ingredient in the innovator's product.

ANSWER: Paragraph 51 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Sandoz admits that the approval requirements for an ANDA are fully set forth in the applicable statute and FDA's implementing rules and

regulations. Except as expressly admitted herein, the allegations of Paragraph 51 are denied.

52. Given its complexity, COPAXONE® 40 mg/mL cannot be fully characterized. Moreover, the method of action of COPAXONE® 40 mg/mL has not been fully elucidated. Thus, while COPAXONE® 40 mg/mL has been demonstrated to be a safe and effective treatment for relapsing- remitting multiple sclerosis, the specific attributes of the product responsible for this safe and efficacious treatment have not been fully identified.

ANSWER: Paragraph 52 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Sandoz admits that the current FDA-approved label states, inter alia: "Glatiramer acetate, the active ingredient of COPAXONE, consists of the acetate salts of synthetic polypeptides, containing four naturally occurring amino acids: L-glutamic acid, L-alanine, L-tyrosine, and L-lysine with an average molar fraction of 0.141, 0.427, 0.095, and 0.338, respectively"; and "The mechanism(s) by which glatiramer acetate exerts its effects in patients with MS are not fully understood. However, glatiramer acetate is thought to act by modifying immune processes that are believed to be responsible for the pathogenesis of MS." Except as expressly admitted herein, the allegations of Paragraph 52 are denied.

53. It is believed that the method of manufacturing COPAXONE® plays a role in the composition of, and therefore the action and effectiveness of Teva's COPAXONE® 40 mg/mL product.

ANSWER: Paragraph 53 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Sandoz denies the allegations of Paragraph 53.

54. Upon information and belief, Sandoz and Momenta have begun to manufacture and/or import commercial batches of Defendants' Glatiramer Acetate Product.

ANSWER: Paragraph 54 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, [redacted]

[redacted] Except as expressly admitted herein, the allegations of Paragraph 54 are denied.

55. Upon information and belief, Defendants must produce their generic glatiramer acetate product using a process that infringes at least one of the claims of the '775 patent in order for the product to be determined by the FDA to be the same as Teva's COPAXONE® 40 mg/mL and to meet any other requirements for FDA approval of Defendants' Glatiramer Acetate Product.

ANSWER: Sandoz denies the allegations of Paragraph 55.

56. Upon information and belief, the processes claimed in the '775 patent are the only commercially feasible means of producing commercial scale quantities of COPAXONE® 40 mg/mL.

ANSWER: Sandoz denies the allegations of Paragraph 56.

57. Upon information and belief, Defendants intend to launch Defendants' Glatiramer Acetate Product upon receiving FDA approval which may occur as early as the first quarter of 2017, prior to the expiration of the '775 patent. *See* https://globenewswire.com/news- release/2017/01/06/904009/0/en/Momenta-Provides-Year-End-2016-Corporate-Update.html, accessed January 9, 2017. Defendants have stated their ANDA will be eligible for approval as early as January 28, 2017.

ANSWER: Paragraph 57 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Sandoz admits that it launched its Glatopa® 20 mg/mL product formulation on or about June 18, 2015 [redacted] Except as expressly admitted herein, the allegations of Paragraph 57 are denied.

COUNT I:
U.S. PATENT NO. 9,155,775

58. The allegation of the preceding paragraphs 1-57 are realleged and incorporated herein by reference.

ANSWER: Sandoz incorporates by reference its responses to the allegations of Paragraphs 1-57 as if fully set forth herein.

59. Upon information and belief, Sandoz currently infringes and has infringed one or more claims of the '775 patent under at least sections (a)-(c) and/or (g) of 35 U.S.C. § 271 by the manufacture, marketing, sale, offer to sell and/or importation of the Sandoz Glatiramer Acetate Product.

ANSWER: Sandoz denies the allegations of Paragraph 59.

60. Upon information and belief, Momenta currently infringes and has infringed one or more claims of the '775 patent under at least sections (a)-(c) and/or (g) of 35 U.S.C. § 271 by the manufacture, marketing, sale, offer to sell and/or importation of the Sandoz Glatiramer Acetate Product.

ANSWER: Paragraph 60 contains legal conclusions and allegations directed to a third party to which no answer is required. To the extent an answer is required, Sandoz denies the allegations of Paragraph 60.

61. Upon information and belief, Defendants have acted in concert by assisting with, participating in, encouraging, contributing, aiding and abetting and/or directing the manufacture, marketing, sale, offer to sell and/or importation of the Sandoz Glatiramer Acetate Product.

ANSWER: Paragraph 61 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Sandoz admits that Sandoz and Momenta are development and commercialization partners for Sandoz's 40 mg ANDA Product. Except as expressly admitted herein, the allegations of Paragraph 61 are denied.

62. Upon information and belief, Defendants' infringement is willful and continues despite knowledge of the '775 patent. Upon information and belief, Defendants acted without a reasonable basis for believing that they would not be liable for infringing the '775 patent.

ANSWER: Sandoz denies the allegations of Paragraph 62.

63. Teva will be substantially and irreparably harmed by Defendants' infringing activities unless the Court enjoins those activities. Teva will have no adequate remedy at law if Defendants are not enjoined from the commercial manufacture, use, offer to sell, sale in and importation into the United States of the Sandoz Glatiramer

Acetate Product. Defendants' activities render this case an exceptional one, and Teva is entitled to an award of their reasonable attorney's fees under 35 U.S.C. § 285.

ANSWER: Sandoz denies the allegations of Paragraph 63.

COUNT II:
U.S. PATENT NO. 9,155,775

64. The allegations of the preceding paragraphs 1-63 are realleged and incorporated herein by reference.

ANSWER: Sandoz incorporates by reference its responses to the allegations of Paragraphs 1-63 as if fully set forth herein.

65. Upon information and belief, Defendants intend to manufacture, market, sell, offer to sell and/or import Defendants' Glatiramer Acetate product upon receiving FDA approval, as early as the first quarter of 2017.

ANSWER: Paragraph 65 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, [redacted] Further answering, Sandoz admits that it launched its Glatopa® 20 mg/mL product formulation on or about June 18, 2015 [redacted] Except as expressly admitted herein, the allegations of Paragraph 65 are denied.

66. Such conduct will constitute direct infringement of the '775 patent under 35 U.S.C. § 271(a), inducement of infringement of the '775 patent under 35 U.S.C. § 271(b), contributory infringement under 35 U.S.C. § 271(c), and/or infringement of the '775 patent under 35 U.S.C. § 271(g).

ANSWER: This paragraph is vague and ambiguous and lacks sufficient specificity under *Bell Atl. Corp. v. Twombly* and *Ashcroft v. Iqbal* and their progeny. *See Bell Atl. Corp. v. Twombly*, 550 U.S. 544 (2007); *Ashcroft v. Iqbal*, 556 U.S. 662 (2009). [redacted] Sandoz has presently pending before the FDA ANDA No. 206921 relating to a 40 mg/mL formulation. Teva has not identified what acts constitute the infringing acts; moreover, the claims of the '775 patent are limited to a method of manufacture. Sandoz denies the allegations of Paragraph 66.

67. As a result of the foregoing facts, there is an imminent, real, substantial, and continuing justiciable controversy between Teva and Defendants as to liability for the infringement of the '775 patent. Defendants' actions have created in Teva a reasonable apprehension of irreparable harm and loss resulting from Defendants' threatened imminent actions.

ANSWER: Sandoz denies the allegations of Paragraph 67. Sandoz affirmatively states that Sandoz's Glatopa® 20 mg/mL product [redacted] filing date of the '775 patent itself.

68. Upon information and belief, Defendants will knowingly and willfully infringe the '775 patent.

ANSWER: Sandoz denies the allegations of Paragraph 68.

69. Teva will be substantially and irreparably harmed by Defendants' infringing activities unless the Court enjoins those activities. Teva will have no adequate remedy at law if Defendants are not enjoined from the commercial manufacture, use, offer to sell, sale in and importation into the United States of the Sandoz Glatiramer Acetate Product. Defendants' activities render this case an exceptional one, and Teva is entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: Sandoz denies the allegations of Paragraph 69. Sandoz affirmatively states that Sandoz's Glatopa® 20 mg/mL product [redacted] filing date of the '775 patent itself.

PRAYER FOR RELIEF

Sandoz denies that Teva is entitled to any of the relief requested in Teva's Prayer for Relief.

SANDOZ'S DEFENSES

Sandoz asserts the following defenses without prejudice to the denials in this Answer, and without admitting any allegations of the Complaint not otherwise specifically admitted herein. Without admitting or implying that Sandoz bears the burden of proof as to any of them, Sandoz, on information and belief, asserts the following separate defenses.

First Defense
(Noninfringement of the '775 patent)

1. The manufacture, use, sale, offer for sale, importation, and/or marketing of the glatiramer acetate ("GA") injection, 20 mg/mL product that is the subject of ANDA No. 90-218 ("Sandoz's 20 mg ANDA Product") has not infringed, does not infringe, and would not—if made, use, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid and/or enforceable claim of the '775 patent, either literally or under the doctrine of equivalents.

2. The manufacture, use, sale, offer for sale, importation, and/or marketing of the GA injection, 40 mg/mL product that is the subject of Sandoz's ANDA No. 20-6921 ("Sandoz's 40 mg ANDA Product") has not infringed, does not infringe, and would not—if made, use, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid and/or enforceable claim of the '775 patent, either literally or under the doctrine of equivalents.

Second Defense
(Noninfringement of the '775 patent–fair use defense)

3. The America Invents Act ("AIA") became effective on September 16, 2011; through it, Congress expressly expanded the scope of the "prior user" defense to process patent

infringement, which is found in 35 U.S.C. § 273, to include manufacturing processes.[1] Not only were the scope of protected processes expanded, but Congress expressly provided that processes presented in documents submitted for "premarketing regulatory review" (*i.e.*, FDA submissions) are "commercial uses" for purposes of the defense. 35 U.S.C. § 273(c).

4. The '775 patent on its face identifies a filing date of January 28, 2015.

5. [redacted]

[1] "The [America Invents] Act broadened the subject matter of the defense [beyond just business method patents] to protect businesses from having to disclose internal processes and technologies." Order at 4, *dunnhumby USA, LLC v. emnos USA Corp.*, Case No. 13-cv-00399, (N.D. Ill. June 27, 2014), Dkt. 106; *see also, e.g.*, 157 CONG. REC. H4483 (daily ed. June 23, 2011) (statement of Rep. Smith) ("The prior-use defense . . . will protect American manufacturers from having to patent the hundreds or thousands of processes they already use in their plants."); 157 CONG. REC. S5426 (daily ed. Sept. 8, 2011) (statements of Sen. Blunt and Sen. Leahy) (discussing that "the prior user rights provided under section 5 of H.R. 1249 will allow developers of innovative technologies to keep internally used technologies in-house without publication in a patent"); 157 CONG. REC. S5430 (daily ed. Sept. 8, 2011) (statement of Sen. Kyl) ("The prior-commercial-use defense provides relief to U.S. manufacturers . . . [by] allowing them to make long-term use of a manufacturing process without having to give it away to competitors or run the risk that it will be patented out from under them.").

[redacted]

10. Paragraph 55 of Teva's Complaint in this action states that Sandoz Inc. and Momenta "must produce their generic glatiramer acetate product using a process that infringes at least one of the claims of the '775 patent," because "processes claimed in the '775 patent are the only commercially feasible means of producing commercial scale quantities of COPAXONE® 40 mg/mL." (Teva's New Jersey Complaint (D.I. 1) ¶¶ 55, 56). [redacted]

Third Defense
(No induced infringement of the '775 patent)

11. Sandoz has not induced, does not induce, and will not induce infringement of any valid and/or enforceable claim of the '775 patent.

Fourth Defense
(No contributory infringement of the '775 patent)

12. Sandoz has not contributed, does not contribute, and will not contribute to infringement of any valid and/or enforceable claim of the '775 patent.

Fifth Defense
(Invalidity of the '775 patent)

13. The '775 patent and each of the claims thereof are invalid for failure to comply with one or more of the conditions for patentability set forth in one or more provisions of 35 U.S.C.

§§ 101, 102, 103, and/or 112, or under other judicially created bases for invalidation, for at least the following reasons.

Anticipation

14. Certain claims of the '775 patent are invalid for anticipation in view of at least US 2013/0323771 A1 and/or US 2007/0054857 Al.

On-Sale Bar

15. The 2011 America Invents Act on-sale bar provision renders patents invalid if the invention was sold prior to patenting even if the sale did not publicly disclose the invention.

16. On June 13, 2007 Momenta filed an 8-K form with the SEC, reporting the "Execution of Collaboration and License Agreement" and further reporting that "[u]nder the terms of the Collaboration Agreement, the Company and Sandoz will exclusively collaborate on the development and commercialization of four follow-on and complex generic products for sale in specified regions of the world." (Momenta Pharmaceuticals, Inc., Form 8-K (June 13, 2007),, https://www.sec.gov/Archives/edgar/data/1235010/000110465907047472/a07-13599_28k.htm). [redacted] On August 9, 2007, Momenta further published a redacted copy of the agreement as an attachment to its 10-Q form for the quarterly period ending June 30, 2007. (Momenta Pharmaceuticals, Inc., Ex. 10.1 to Form 10-Q (Aug. 9, 2007), https://www.sec.gov/Archives/edgar/data/1235010/000110465907060901/a07-18893_1ex10d1.htm).

17. The '775 patent on its face identifies a filing date of January 28, 2015.

18. As noted above, Teva's New Jersey Complaint alleged that Sandoz Inc. and Momenta "must produce their generic glatiramer acetate product using a process that infringes at least one of the claims of the '775 patent," because "processes claimed in the '775 patent are the only commercially feasible means of producing commercial scale quantities of COPAXONE® 40

mg/mL." (Teva's New Jersey Complaint (D.I. 1) ¶¶ 55, 56).

19. If such Teva infringement allegations were to be accepted as true, then the June 13, 2007 and August 9, 2007 disclosures to the SEC of the Sandoz-Momenta Collaboration and License Agreement automatically constitutes a qualifying public sale of the invention claimed by the '775 patent. At least one Teva plaintiff here has argued similar disclosures can evidence a sale. *See, e.g.*, *Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc.*, 855 F.3d 1356, 1363-67, (Fed. Cir. 2017).

Obviousness

20. The '775 patent is invalid under 35 U.S.C. § 103 in view of at least the following prior art: U.S. Patent Application Publication No. 2013/0323771 A1 to Dhananjay Govind Sathe et al.; U.S. Patent Application Publication No. 2007/0054857 A1 to Irit Pinchasi et al.; International Publication No. WO 2007/081975 A2 to Irit Pinchasi; Copaxone® Label (revised Jan. 2014); *Corning® Filtration Guide* (Jan. 2013), https://www.corning.com/media/worldwide/cls/documents/CLS-FIL-004%20REV4%20DL.pdf; Daniel J. Brose et al., *Membrane Filtration*, *in* DEVELOPMENT AND MANUFACTURE OF PROTEIN PHARMACEUTICALS 213 (Nail & Akers eds., 2002); Maik W. Jornitz & Theodore H. Meltzer, *Media and Buffer Filter Implications*, *in* 174 DRUGS AND THE PHARMACEUTICAL SCIENCES, FILTRATION AND PURIFICATION IN THE BIOPHARMACEUTICAL INDUSTRY 439 (Maik W. Jornitz & Theodore H. Meltzer eds., 2d ed. 2008); Joerg Gsponer & Michele Vendruscolo, *Theoretical Approaches to Protein Aggregation*, 13 PROTEIN & PEPTIDE LETTERS 287 (2006); James A. Akers, *Microbiological Considerations in the Selection and Validation of Filter Sterilization*, *in* 174 DRUGS AND THE PHARMACEUTICAL SCIENCES, FILTRATION AND PURIFICATION IN THE BIOPHARMACEUTICAL INDUSTRY 151 (Maik W. Jornitz & Theodore H. Meltzer eds., 2d ed. 2008);

Frances W. Bowman et al., *Microbiological Methods for Quality Control of Membrane Filters*, 56 J. PHARM. SCI. 222 (1967); 4 EUROPEAN COMMISSION, EU GUIDELINES TO GOOD MANUFACTURING PRACTICE, MEDICINAL PRODUCTS FOR HUMAN AND VETERINARY USE, ANNEX 1, MANUFACTURE OF STERILE MEDICINAL PRODUCTS (Nov. 25, 2008); U.S. DEP'T HEALTH & HUMAN SERVS., FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY, STERILE DRUG PRODUCTS PRODUCED BY ASEPTIC PROCESSING (Sept. 2004); MAIK W. JORNITZ & THEODORE H. MELTZER, STERILE FILTRATION – A PRACTICAL APPROACH (2011); Jerold M. Martin & Richard L. Manteuffel, *Protein Recovery from Effluents of Microporous Membranes*, BIOPHARM 20 (1988); Theodore H. Meltzer & Maik W. Jornitz, *Filter Sizing: The Requirements and Their Attainment*, *in* 174 DRUGS AND THE PHARMACEUTICAL SCIENCES, FILTRATION AND PURIFICATION IN THE BIOPHARMACEUTICAL INDUSTRY 163 (Maik W. Jornitz & Theodore H. Meltzer eds., 2d ed. 2008); Harwood Green & Theodore H. Meltzer, *Flow and Pressure, Filter Sizing, and Filter System Design*, *in* FILTRATION IN THE PHARMACEUTICAL INDUSTRY 409 (1987); Theodore H. Meltzer, *Protein Adsorption by Polymeric Filters*, *in* 174 DRUGS AND THE PHARMACEUTICAL SCIENCES, FILTRATION AND PURIFICATION IN THE BIOPHARMACEUTICAL INDUSTRY 257 (Maik W. Jornitz & Theodore H. Meltzer eds., 2d ed. 2008); MEMBRANES FOR LIFE SCIENCES (Klaus-Viktor Peinemann & Suzana Pereira Nunes eds., 2008); Technical Report No. 26, *Sterilizing Filtration of Liquids*, 52 PDA J. PHARM. SCI. & TECH. 1 (Supp. 1998); Paul S. Stinavage, *Validation of the Filter and of the Filtration Process, in* 174 DRUGS AND THE PHARMACEUTICAL SCIENCES, FILTRATION AND PURIFICATION IN THE BIOPHARMACEUTICAL INDUSTRY 371 (Maik W. Jornitz & Theodore H. Meltzer eds., 2d ed. 2008); George A. Truskey et al., *The Effect of Membrane Filtration Upon Protein Conformation*, 41 J. PARENTERAL SCI. & TECH. 180 (1987); UNITED STATES PHARMACOPEIA 36, NATIONAL FORMULARY 31 (2013); Masihuz Zaman et al., *Nanoparticles in*

Relation to Peptide and Protein Aggregation, 9 INT'L J. NANOMEDICINE 899 (2014); Sartorius Stedim Biotech GmbH, Data Sheet: Sartobran® P 0.2 µm Sterilizing Grade Filter Cartridges (2014).

Section 112 Defenses

21. The claims of the '775 patent are indefinite.

22. The claims of the '775 patent are not fully enabled.

23. The claims of the '775 patent lack utility across the full scope of what is claimed and/or are inoperable across the full scope of what it is claimed.

24. The claims of the '775 patent include terms that are indefinite.

25. The claims of the '775 patent encompass subject matter for which there is no written description support.

26. Sandoz reserves the right to pursue discovery to ascertain whether Teva sought to derive any aspect of its claims from prior work by Momenta/Sandoz, as Teva had possession of the Sandoz ANDA prior to filing the '775 patent.

Sixth Defense
(Surrender)

27. Teva's Complaint should be dismissed to the extent it seeks to assert any claims beyond claim 21, given its decision to drop all claims except claim 21 in its infringement assertions on the merits while this case was pending in the U.S. District Court for the District of New Jersey.

Seventh Defense
(Failure to State a Claim)

28. The Complaint fails to state a claim upon which relief can be granted.

Eighth Defense
(Equitable Estoppel)

29. Plaintiffs' claims are barred in whole or in part by the doctrine of equitable estoppel.

30. For example, Plaintiffs have been in litigation with Sandoz and Momenta involving the 20 mg and 40 mg GA ANDA products well prior to the point in time when the patent-in-suit was filed in the United States Patent Office. Despite multiple opportunities to file suit; aggressively litigating against Sandoz and Momenta; and asserting newly-issued patents within weeks, for the '775 patent, Teva made no effort to assert any claim of infringement; such silence was misleading; relied upon by Sandoz and Momenta; and Sandoz and Momenta are prejudiced by Plaintiffs' late assertion of the '775 patent.

Ninth Defense
(Failure to State a Claim for Willful Infringement and/or Exceptional Case)

31. The Complaint fails to state a claim for willful infringement and/or exceptional case.

Tenth Defense
(No Injunctive Remedy for the '775 Patent)

32. Sandoz repeats and incorporates by reference each of the foregoing paragraphs of its Answer and Defenses to Teva's Complaint.

33. Neither the patent holder nor its exclusive licensee will in fact experience any harm from any Sandoz Inc. sales of the GA40 product that has nexus to the '775 patent claims.

34. Teva has unacceptably delayed in asserting the '775 patent.

35. Teva cannot demonstrate any alleged harm that is irreparable or otherwise not compensable via monetary damages even if infringement of a valid and enforceable patent were presumed.

36. Teva is not entitled to any injunctive remedy of any kind.

Eleventh Defense
(Miscellaneous Reservation of Rights)

37. Sandoz asserts the above defenses without the benefit of discovery, and reserves the right to assert any additional defenses or counterclaims that discovery may reveal, including unenforceability and/or unclean hands.

SANDOZ'S COUNTERCLAIMS

Defendant and Counterclaim-Plaintiff Sandoz Inc. ("Sandoz") hereby alleges the following Counterclaims against Plaintiffs and Counterclaim-Defendants Teva Pharmaceuticals USA, Inc.; Teva Pharmaceutical Industries Ltd.; and Teva Neuroscience, Inc. (collectively "Teva").

1. Sandoz repeats and incorporates by reference each of the foregoing paragraphs of Sandoz's Answer and Defenses to Teva's Complaint.

THE PARTIES

2. Sandoz Inc. is a corporation organized under the laws of the State of Colorado. Sandoz's corporate headquarters are located at 100 College Road West, Princeton, NJ, 08540.

3. On information and belief, and based on the allegations in the Complaint, Teva Pharmaceutical Industries Ltd. ("Teva Ltd.") is an Israeli company with its principal place of business at 5 Basel Street, P.O. Box 3190, Petah Tikva, 49131, Israel.

4. On information and belief, and based on the allegations in the Complaint, Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation with its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454-1090. On information and belief, Teva USA is a subsidiary controlled by Teva Ltd.

5. On information and belief, based on the allegations in the Complaint, Teva Neuroscience, Inc. ("Teva Neuroscience") is a Delaware corporation with its principal place of business at 11100 Nall Ave., Overland Park, Kansas 66211. On information and belief, Teva

Neuroscience is a subsidiary controlled by Teva Ltd.

JURISDICTION

6. These Counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 100 et seq. This Court has subject matter jurisdiction over these Counterclaims pursuant to 28 U.S.C. §§ 1331, 1338, 2201, and/or 2202.

7. This Court has personal jurisdiction over each of Teva Ltd.; Teva USA; and Teva Neuroscience because they have subjected themselves to the jurisdiction of this Court by filing the Complaint and by filing a complaint in related actions, including *Teva Pharm. USA, Inc. et al. v. Sandoz Inc. et al.*, 14-cv-01171-GMS (D. Del.); *Teva Pharm. USA, Inc. et al. v. Dr. Reddy's Labs. Ltd. et al.*, 14-cv-01172-GMS (D. Del.), which concern the '250, '413, '302, and '776 patents; *Teva Pharm. USA, Inc. et al. v. Dr. Reddy's Labs. Ltd. et al.*, 15-cv-00306-GMS (D. Del.), which concerns the '302 patent; and *Teva Pharm. USA, Inc. et al. v. Dr. Reddy's Labs. Ltd. et al.*, 16-cv-01267-GMS (D. Del.), which concerned the '874 patent.

8. Upon information and belief, on October 13, 2015, the United States Patent and Trademark Office ("PTO") issued U.S. Patent No. 9,155,775 ("the '775 patent"), entitled "Process for Manufacturing Glatiramer Acetate Product." The '775 patent lists, on its face Rakefet Cohen, Sasson Habbah, and Muhammad Safadi as purported inventors of the patent.

9. Teva Pharmaceutical Industries, Ltd. is listed as the purported assignee on the face of the '775 patent.

10. Venue as to these Counterclaims is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400.

FACTUAL BACKGROUND

Glatiramer Acetate and the '775 Patent

11. Glatiramer acetate ("GA") (formerly known as copolymer-1) is the active

ingredient in COPAXONE®, a multiple sclerosis ("MS") drug manufactured and marketed by Teva. Copolymer-1 was first developed in 1967.

12. Copolymer-1 was the subject of U.S. Patent Application Serial No. 240,244, filed in the U.S. on March 31, 1972. It claimed priority from an Israeli Application (No. 36,670) filed on April 21, 1971, and issued as U.S. Patent No. 3,849,550 on November 19, 1974 ("the '550 patent").

13. Copaxone® for solution; subcutaneous, 20 mg/vial was approved on December 20, 1996.

14. Copaxone® injectable; subcutaneous, 20 mg/ml was approved on February 12, 2002.

15. Copaxone® injectable; subcutaneous, 40 mg/ml was approved on January 28, 2014.

16. It is well known in the art that parental dosage forms, such as Copaxone®, are strictly required by FDA to be sterile.

17. The 2001 label for Copaxone® states that "[t]he recommended storage condition for the unreconstituted product is refrigeration (2°C to 8°C / 36°F to 46°F)."

18. The 2009 label for Copaxone® states that "[t]he recommended storage condition for the COPAXONE is refrigeration (2°C to 8°C / 36°F to 46°F)."

19. The 2013 label for Copaxone® states that "[t]he recommended storage condition for the COPAXONE is refrigeration (2°C to 8°C / 36°F to 46°F)."

20. The 2014 label for Copaxone states "[s]tore COPAXONE refrigerated at 2°C to 8°C (36°F to 46°F)."

21. The application leading to the '775 patent (App. Ser. No. 14/608,126) was filed on January 28, 2015.

Sandoz and Momenta's Products and Product Development

22. On June 13, 2007, Momenta filed an 8-K form with the SEC, reporting the "Execution of Collaboration and License Agreement" and further reporting that "[u]nder the terms of the Collaboration Agreement, the Company and Sandoz will exclusively collaborate on the development and commercialization of four follow-on and complex generic products for sale in specified regions of the world." (Momenta Pharmaceuticals, Inc., Form 8-K (June 13, 2007),, https://www.sec.gov/Archives/edgar/data/1235010/000110465907047472/a07-13599_28k.htm). [redacted] On August 9, 2007, Momenta further published a redacted copy of the agreement as an attachment to its 10-Q form for the quarterly period ending June 30, 2007. (Momenta Pharmaceuticals, Inc., Ex. 10.1 to Form 10-Q (Aug. 9, 2007), https://www.sec.gov/Archives/edgar/data/1235010/000110465907060901/a07-18893_1ex10d1.htm).

23. On December 26, 2007, Sandoz submitted ANDA No. 90-218 ("the Sandoz 20 mg ANDA" or "Sandoz's 20 mg ANDA") to the FDA seeking approval to manufacture and sell glatiramer acetate injection 20 mg/mL ("Sandoz's 20 mg ANDA Product").

24. The America Invents Act ("AIA") became effective on September 16, 2011; through it, Congress expressly expanded the scope of the "prior user" defense to process patent infringement, which is found in 35 U.S.C. § 273, to include manufacturing processes.[2] Not only

[2] "The [America Invents] Act broadened the subject matter of the defense [beyond just business method patents] to protect businesses from having to disclose internal processes and technologies." Order at 4, *dunnhumby USA, LLC v. emnos USA Corp.*, Case No. 13-cv-00399, (N.D. Ill. June 27, 2014), Dkt. 106; *see also, e.g.*, 157 CONG. REC. H4483 (daily ed. June 23, 2011) (statement of Rep. Smith) ("The prior-use defense . . . will protect American manufacturers from having to patent the hundreds or thousands of processes they already use in their plants."); 157 CONG. REC. S5426 (daily ed. Sept. 8, 2011) (statements of Sen. Blunt and Sen. Leahy) (discussing that "the prior user rights provided under section 5 of H.R. 1249 will allow developers of innovative technologies to keep internally used technologies in-house without publication in a patent"); 157 CONG. REC. S5430 (daily ed. Sept. 8, 2011) (statement of Sen. Kyl) ("The prior-commercial-use defense provides relief to U.S. manufacturers . . . [by] allowing them to make long-term use of a

were the scope of protected processes expanded, but Congress expressly provided that processes presented in documents submitted for "premarketing regulatory review" (*i.e.*, FDA submissions) are "commercial uses" for purposes of the defense. 35 U.S.C. § 273(c).

25. [redacted] Sandoz submitted ANDA No. 20-6921 ("the Sandoz 40 mg ANDA" or "Sandoz's 40 mg ANDA") to the FDA seeking approval to manufacture and sell glatiramer acetate injection 40 mg/mL ("Sandoz's 40 mg ANDA Product").

26. [redacted]

27. On April 16, 2015, the FDA approved Sandoz's 20 mg ANDA.

28. On or around June 18, 2015, Sandoz began selling its 20 mg ANDA Product, Glatopa®, to the public.

29. [redacted]

30. [redacted]

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manufacturing process without having to give it away to competitors or run the risk that it will be patented out from under them.").

[redacted] Paragraphs 55 and 56 of Teva's Complaint in this action state that Sandoz Inc. and Momenta "must produce their generic glatiramer acetate product using a process that infringes at least one of the claims of the '775 patent," because "processes claimed in the '775 patent are the only commercially feasible means of producing commercial scale quantities of COPAXONE® 40 mg/mL." (Teva's New Jersey Complaint (D.I. 1) ¶¶ 55, 56).

31. [redacted]

32. [redacted] Such commercial use (including as defined by 35 U.S.C. § 273(c)(1)), likewise involved arm's length commercial transfers on or before January 28, 2014.

FIRST COUNTERCLAIM
(Declaratory Judgment of Noninfringement of the '775 Patent)

33. Sandoz hereby incorporates by reference its Answer to Plaintiffs' Complaint, including its Affirmative Defenses, and also Paragraphs 1 through 32 of these Counterclaims above.

34. This Counterclaim arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court exists between Sandoz and Counterclaim-Defendants concerning the infringement of the '775 patent.

35. Sandoz's manufacture, use, offer for sale, sale, importation, and/or marketing of its 20 mg and 40 mg ANDA products has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the '775 patent, either literally or under the doctrine of equivalents.

36. Counterclaim-Defendants bear the burden of proving by a preponderance of the evidence that every limitation set forth in the asserted claim is found in the accused product, either literally or by a substantial equivalent. To date, Counterclaim-Defendants have not set forth any evidence attempting to prove infringement of each and every element of the '775 patent with regard to the process used to prepare the Sandoz ANDA product.

37. Sandoz is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, importation, and/or marketing of its 20 mg and 40 mg ANDA products have not infringed, do not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the '775 patent, either literally or under the doctrine of equivalents.

SECOND COUNTERCLAIM

(Declaratory Judgment of Non-infringement of the '775 patent–Fair Use Defense)

38. Sandoz hereby incorporates by reference its Answer to Plaintiffs' Complaint, including its Affirmative Defenses, and also Paragraphs 1 through 37 of these Counterclaims above.

39. Sandoz is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, importation, and/or marketing of its 20 mg and 40 mg ANDA Products have not infringed, do not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the '775 patent because

said activities are protected by the fair use doctrine.

THIRD COUNTERCLAIM
(Declaratory Judgment of Invalidity of the '775 Patent)

40. Sandoz hereby incorporates by reference its Answer to Plaintiffs' Complaint, including its Affirmative Defenses, and also Paragraphs 1 through 39 of these Counterclaims above.

41. The claims of the '775 patent are invalid for failure to comply with the requirements of patentability as specified in 35 U.S.C. §§ 1 *et seq.*, including, without limitation, 35 U.S.C. §§ 101, 102, 103, 112, and/or 120, and/or based on other judicially-created bases for invalidation.

42. Upon information and belief, such defenses include those set forth in its Affirmative Defenses above (and incorporated by reference herein), which includes, but is not limited to, that the '775 patent lacks utility across the full scope of what is claimed and/or is inoperable across the full scope of what it is claimed; is invalid for prior use and/or being on sale; is anticipated; would have been obvious to the person of ordinary skill in the art; includes claims with claim terms that are indefinite; encompasses subject matter for which there is no written description support; and the full scope of the claims is not fully enabled (at least for encompassing embodiments that lack operability).

43. Sandoz reserves the right to provide additional bases for invalidity of the '775 patent in its contentions, responses to discovery requests, expert reports, and/or pleadings filed and/or served later in this action.

44. Sandoz is entitled to a judicial declaration that the claims of the '775 patent are invalid.

FOURTH COUNTERCLAIM
(No Injunctive Remedy for the '775 Patent)

45. Sandoz hereby incorporates by reference its Answer to Plaintiffs' Complaint, including its Affirmative Defenses, and also Paragraphs 1 through 44 of these Counterclaims above.

46. Neither the patent holder nor its exclusive licensee will in fact experience any harm from any Sandoz sales of the GA40 product that has nexus to the '775 patent claims.

47. Teva has unacceptably delayed in asserting the '775 patent.

48. Teva cannot demonstrate any alleged harm that is irreparable or otherwise not compensable via monetary damages even if infringement of a valid and enforceable patent were presumed.

49. Teva is not entitled to any injunctive remedy of any kind.

FIFTH COUNTERCLAIM
(Miscellaneous Reservation of Rights)

50. Defendants assert the above Counterclaims without the benefit of full discovery and investigation, and reserve the right to supplement or amend these Counterclaims as necessary.

PRAYERS FOR RELIEF

WHEREFORE, Sandoz prays:

A. That this Court find and declare that the making, using, selling, offering for sale, marketing, or importation of Sandoz's 20 mg and 40 mg ANDA Products, and any actions by Sandoz relating thereto, does not and will not directly or indirectly infringe, or induce or contribute to the infringement of, any valid claim of the '775 patent;

B. That this Court find and declare that Sandoz is permitted to use its pre-existing ANDA process conditions to prepare GA20 and GA40 under the fair use provisions of 35 U.S.C. § 273;

C. That this Court find and declare that the '775 patent and all of its claims are invalid and unenforceable;

D. That this Court enjoin Teva, and its agents, representatives, attorneys, and those persons in active concert or participation with them who receive actual notice hereof, from threatening or initiating infringement litigation against Sandoz, or

its customers, dealers, or suppliers, or any prospective or present sellers, dealers, distributors, or customers of the Sandoz 20 mg and 40 mg ANDA Products, or charging them either orally or in writing with infringement of the '775 patent;

E. That this Court award Sandoz all of its costs for this action;

F. That this Court find this case to be exceptional under 35 U.S.C. § 285 or otherwise and awarding Sandoz its costs and reasonable attorneys' fees; and

G. That this Court grant Sandoz such other and further relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Sandoz Inc. hereby demands a jury trial on all issues so triable.

Dated: June 9, 2017

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CERTIFICATE OF SERVICE

I, Dominick T. Gattuso, Esquire, hereby certify that on the 9th day of June, 2017, copies of Defendant Sandoz Inc.'s Answer, Defenses and Counterclaims were served upon plaintiffs' counsel of record via electronic mail.

/s/ *Dominick T. Gattuso*
Dominick T. Gattuso (# 3630)